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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,153	03/14/2005	Mikio Suzuki	Q82789	5702
23373 7590 10/10/2007 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER ZARA, JANE J	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 10/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/505,153

Applicant(s)

SUZUKI ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-30 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) 16,19-30,36,37,39 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-15 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7-28-05.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: See Alignment Data

DETAILED ACTION

This Office action is in response to the communication filed 7-26-07.

Claims 1-5, 7-30 and 36-40 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-15, 17, 18, 35 and 38 in the reply filed on 7-26-07 is acknowledged. The traversal is on the ground(s) that no undue burden would exist to search all of the inventions and all of the sequences claimed. This is not found persuasive because the different and distinct invention encompass distinct techniques and distinct products requiring searches that would not be coextensive, as well as consideration of written description and enablement issues for each invention claimed. Searching all of the different inventions claimed would indeed pose an undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16, 19-30, 36, 37, 39 and 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7-26-07.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-15 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 6-9, it is unclear what is meant by a target gene having "RNA suppression activity in relation to RNA having a sequence complementary to either component (I) or (III) or a partial sequence thereof." The metes and bounds of the claimed invention cannot be determined. Appropriate correction is required.

In claim 38, lines 3-7, the claim recites "1 to 5 ribonucleotides continuing at 18-25 ribonucleotides complementary to the target gene, and component (I) comprises 18 to 25 ribonucleotides complementary to the 18 to 25 nucleotides complementary to the 18 to 25 ribonucleotides of component (III)." It is not clear what is being claimed here. Therefore, the metes and bounds of claim 38 cannot be determined. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-15, 17, 18 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims appear to be drawn to an RNAi molecule, or a partially self-complementary polynucleotide which targets SEQ ID No. 1, or includes SEQ ID No. 1 in the self-complementary portion of the polynucleotide construct, also having a looped out portion (part II of the claimed construct) that optionally comprises between 1 nucleotide and 10 kilobases in length, and the self-complementary, or partly self-complementary portions (parts I and III) which optionally comprise from one to several U, T, G, C, or A bases (which are either additional bases, or deleted bases, see claim 3, lines 3-5). The polynucleotide also optionally comprises a sequence having decoy activity, a sequence having any of RNase suppression activity, antisense activity, ribozyme activity or transfer RNA, or any combinations thereof (see claim 12).

The specification and claims do not adequately describe elements which appear to be essential to the claimed invention. The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of these broad genera of nucleic acids claimed, encompassing a looped out portion that optionally comprises between 1 nucleotide and 10 kilobases in length, and a self-complementary, or partly self-complementary portion which optionally comprises from 1 to several U, T, G, C, or A bases, which are either additional bases or deleted bases, and optionally further comprising any sequence having decoy activity, or having any of RNase suppression, antisense, ribozyme activities, or transfer RNA, or any combinations thereof.

The disclosure does not clarify what common attributes are encompassed by these highly variable structures, including additions and deletions of nucleotides, loops

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ranging greatly in size, partially or fully self-complementary sequences, antisense, ribozymes, RNase suppressors, transfer RNAs and combinations thereof. The scope of the claims includes numerous structural variants, and the genera are highly variant because a significant number of structural differences between members is permitted. Concise structural features, that could distinguish structures or compounds within each genus from those outside of a given genus, are missing from the disclosure. No common structural attributes identify the members of any genus comprising this myriad of nucleic acid variants. And the general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. The specification fails to teach or adequately describe a representative number of species in the various genera of compounds claimed, such that the common attributes or characteristics concisely identifying members of each proposed genus are exemplified. And because the many genera are highly variant, the description provided is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the multitude of polynucleotides claimed. Thus, applicant was not possession of the claimed genera.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7, 12-15, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Tuschl et al (WO 2001/75164).

Tuschl teaches methods of manufacturing and using compositions comprising expression vectors encoding RNAi polynucleotides comprising three portions and having between 15-30 nucleotides, where two portions are self-complementary, comprising the target sequence of SEQ ID No. 1, and wherein some bases in portions I or III are deleted, substituted or added, which polynucleotide comprises DNA and RNA (see example 5, fig. 14B, Accession No. AAS16113).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
9-28-07


JANE ZARA, PH.D.
PRIMARY EXAMINER